

Brussels, 10 April 2015

Statement from FABI members in response to the public consultation on potential candidates for substitution for formaldehyde in PT 3

The members of the Formaldehyde Biocide Interest Group (FABI) would like to submit the below expert statement regarding the essential use of formaldehyde as a biocide for veterinary hygiene (PT3).

FABI is a CEFIC registration group representing all European producers of formaldehyde and formaldehyde releasers participating in the Biocidal Products Regulation (BPR) Review Programme. FABI members strongly recommend taking into account the considerations laid out in this expert statement in view of the preparation of the opinion of the Biocidal Products Committee for formaldehyde and product-type 3.

For further information, please contact:

Flore Cognat – Phone: +32 2 676 7203 – Email: fco@cefic.be

**The use of formaldehyde as a biocide for veterinary hygiene (PT3) and its
impact on animal and human health**

Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Hanover, Germany

On 25 February 2015

1. Introduction

Infectious diseases of animals are caused by bacteria, viruses and fungi; some of the pathogens have an epidemic potential such as *Salmonella* infection of poultry flocks, swine fever, foot-and-mouth disease of bovine and avian influenza (Kijlstra et al., 2006). The protection of animals from infectious diseases is an extremely important part of commercial farming, for food safety and toward the prevention of zoonotic infections transmitted to humans.

For example, *Salmonella* is the leading cause of hospitalisations (28%) and deaths (35%) attributed to known bacterial pathogens transmitted by foods in the United States (Scallan et al 2011). This pathogen is capable of surviving extended starvation and desiccation stresses and has caused major disease outbreaks associated with foods of low water activity (Podolak et al 2010). In livestock housing *Salmonella* persist for long periods and may even multiply upon stock change if moisture is added or the houses are restocked (Gradel and Rattenborg 2003).

For decontamination purposes of livestock housing and equipment several methods can be applied. Especially Formaldehyde has a broad efficacy range and can therefore be most effectively used as a preservative and a broad-spectrum microbicide for the disinfection of air, surfaces, inanimate objects and materials and equipment in veterinary hygiene areas. Hence it enables a high degree of control of infectious diseases in animal farming (Bodenschatz 2006, Kramer & Assadian 2008).

2. Formaldehyde and its use as a disinfectant in veterinary hygiene

Formaldehyde has been used as decontamination treatment in animal farming and in poultry flocks over many decades. It is a biocidal active substance with extraordinary antimicrobial efficacy which provides long lasting residual protection with a good compatibility towards material and disinfection influencing factors.

In disinfection of animal houses it offers a more complete means of protection aiming to control the infectious disease and to prevent proliferation/spread of infectious diseases. It is widely used as a single decontamination treatment, as well as in combination with other agents for disinfection of houses, vehicles and equipment to protect animals from infectious diseases and to prevent transmission or recurring outbreaks.

Commercial biocidal products contain approx. up to 35 – 37% formaldehyde. Formaldehyde is applied in closed rooms at concentration of 2–7.5 % solution, in general, or as fume at 5 g/m³ with a relative humidity of 70 % (Desinfektionsrichtlinie BMELV, Desinfektionmittelliste RKI).

3. Microbiological efficacy and substance properties of formaldehyde

In comparison to other agents formaldehyde has a more comprehensive microbial efficacy range including gram positive and negative bacteria, mycobacteria, spores, fungi and viruses (Bodenschatz 2006, Kramer & Assadian 2008).

Formaldehyde has good compatibility to materials as well as superior compatibility to several influencing factors like the pH value, the presence of albumin, increased water hardness and the presence of metal ions, anionic surfactants and organic matter, inevitably present in farming houses (Bodenschatz 2006, Wallhäußer 1995, Dvorak 2005).

The efficacy of formaldehyde covers a pH range of 4–9 (Bodenschatz 2006, Kramer & Assadian 2008). When fumigated, the substance can reach all inaccessible areas and crevices in the animal facility due to its superior penetration properties.

4. Consideration of risk to humans and environment from the use of formaldehyde in room/house disinfection

Risks to humans or the environment from exposure to formaldehyde are not expected from the specified use as disinfectant in livestock houses, containers or vehicle disinfection.

This is because formaldehyde containing products are only applied in closed rooms/houses without animal or human contact. This is managed by using automated, computer controlled application devices. Disinfection regimes using formaldehyde are conducted by professionals only.

The handling (charging/loading, starting, stopping) of the automated disinfection regime requires full personal protection equipment (PPE) which prevents human contact with the active substance during operation. Following decontamination, residues of formaldehyde on surfaces and treated equipment represent little or no risk, due to rapid chemical and biological degradation.

5. Summary of the essential use of formaldehyde in veterinary hygiene (PT3)

Contaminated livestock houses, equipment, container and vehicles by pathogens are the source of infections for farm animals. This may have severe impact on animal welfare, economic interests and human health.

The use of formaldehyde is still beneficial due to its favourable characteristics including its extraordinary and superior antimicrobial efficacy, the compatibility to several materials, the rapid degradation and other influencing factors and due to the practical ability to be fumigated or fogged.

The application of formaldehyde in veterinary hygiene is essential as there is not an adequate range of alternatives available to minimise the risk of microbial contaminations. Formaldehyde is indicated to prevent several animal and zoonotic diseases including highly contagious and highly infectious diseases that require most efficient decontamination.

For the intended use in animal hygiene, formaldehyde is applied in a safe way without risk to humans and the environment.

6. References

Bodenschatz 2006. Kompaktwissen Desinfektion Das Handbuch für Ausbildung und Praxis
Hrsg. v. Walter Bodenschatz

Gradel K.O., Heat as a disinfection method for poultry houses persistently infected with *Salmonella* – an outline of methods and results. Disinfection in Animal Production Symposium, 18 November 2003, Aarhus, Denmark

Kijlstra A. and I.A.J.M. Eijck, Animal health in organic livestock production systems: a review, NJAS 54-1, 2006

Kramer M, Assadian O (2008). Wallhäußers Praxis der Sterilisation, Desinfektion, Antiseptik und Konservierung: Qualitätssicherung der Hygiene in Industrie, Pharmazie und Medizin. Thieme Verlag.

Wallhäußer K.H. „Praxis der Sterilisation, Desinfektion, Konservierung, Keimidentifizierung, Betriebshygiene, Thieme Verlag 1995